

DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800
Marshall S. Huebner
Benjamin S. Kaminetzky
Timothy Graulich
James I. McClammy
Eli J. Vonnegut

*Counsel to the Debtors
and Debtors in Possession*

**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:

**PURDUE PHARMA L.P., et al.,

Debtors.¹**

Chapter 11

Case No. 19-23649 (RDD)

(Jointly Administered)

**DECLARATION OF JAMES I. MCCLAMMY IN SUPPORT OF THE DEBTORS’
STATEMENT IN RESPONSE TO THE REPLY OF THE NAS CHILDREN AD HOC
AND SUPPLEMENTAL DECLARATION IN FURTHER SUPPORT OF ITS REQUEST
FOR ENTRY OF A COURT ORDER AUTHORIZING EXAMINATIONS PURSUANT
TO FEDERAL RULES OF BANKRUPTCY PROCEDURE 2004 AND 9006**

I, James I. McClammy, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

¹ The Debtors in these cases, along with the last four digits of each Debtor’s registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717), and SVC Pharma Inc. (4014). The Debtors’ corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

1. I am a partner of the law firm Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, New York 10017, counsel for the Debtors in the above-captioned action. I respectfully submit this Declaration in support of the *Debtors' Statement in Response to the Reply of the NAS Children Ad Hoc and Supplemental Declaration in Further Support of Its Request for Entry of a Court Order Authorizing Examinations Pursuant to Federal Rules of Bankruptcy Procedure 2004 and 9006*² filed contemporaneously herewith.

2. The Debtors have been engaging informally with the NASC for approximately a year on discovery issues, meeting and conferring no less than 13 times and exchanging related correspondence.

3. On April 17, 2020, the Debtors received the NASC's first draft Rule 2004 Motion and request to meet and confer regarding various discovery issues (the "**April 2020 Draft Rule 2004 Motion**"). The April 2020 Rule 2004 Motion contained five interrogatories regarding scientific studies and disclosures made to the FDA, as well as four requests for production regarding scientific studies and documents that hit on eight search terms, including "Neonatal Abstinence Syndrome," "NAS," "infant," and "in utero." The Debtors met and conferred with the NASC regarding these requests on April 21, 2020.

4. On April 24, 2020, the Debtors responded to the interrogatories and requests for production in the April 2020 Draft Rule 2004 Motion, directing the NASC to specific Bates ranges in productions to which the NASC has access where it could find (i) the New Drug Applications ("**NDA**") files for OxyContin, Hysingla ER, and Butrans, (ii) lists of studies and clinical trials related to safety and efficacy, (iii) scientific research on which it relied for

² Except where otherwise indicated, capitalized terms used herein but not defined have the meanings ascribed to them in the Debtors' statement.

marketing statements related to eight different topics, (iv) Adverse Event Reports which include clinical observations of in utero exposure, if any, to the compounds under study, and (v) MedWatch Reports, which are reports that reflect adverse events but do not contain enough information to create formal Adverse Event Reports. Attached hereto as **Exhibit 1** is a true and correct copy of the email from J. Knudson to S. Markowitz, dated April 24, 2020. Given the broad nature of certain requests for production, the Debtors were unable to provide specific Bates ranges but explained how the NASC could find the requested documents by reviewing the Bates ranges provided in connection with other requests and conducting searches of the productions using titles, authors, cites, or key words.

5. On May 5, 2020, the NASC told the Debtors that it was unable to find certain Bates-stamped documents. The Debtors informed the NASC that the referenced documents were produced in the Debtors' "data room" for these chapter 11 cases, to which the NASC has access. Attached hereto as **Exhibit 2** is a true and correct copy of the email from J. Knudson to S. Markowitz, dated May 5, 2020. After the NASC noted that it was still unable to find the documents, the Debtors sent the NASC a direct link to the exact documents it was unable to locate. Attached hereto as **Exhibit 3** is a true and correct copy of the email from C. Oluwole to S. Markowitz, *et al.*, dated May 19, 2020.

6. On August 10, 2020, the NASC sent the Debtors a letter regarding the Debtors' April 24, 2020 responses to the April 2020 Rule 2004 Motion and requested to meet and confer on outstanding issues. Attached hereto as **Exhibit 4** is a true and correct copy of the letter from S. Markowitz to J. McClammy & J. Knudson, dated August 10, 2020 ("**August 10, 2020 Letter**"). The Debtors met and conferred with the NASC on August 13, 2020, and September 18, 2020 regarding outstanding issues. In advance of the September 18, 2020 meet and confer,

the Debtors provided the NASC with the Bates ranges for the Oxycodone studies it was unable to locate. Attached hereto as **Exhibit 5** is a true and correct copy of the email from J. Knudson to K. Thompson, dated September 9, 2020.

7. On September 30, 2020, in response to the August 10, 2020 Letter, and subsequent correspondence following the September 18, 2020 meet and confer, the Debtors (i) provided the NASC with E-bates numbers for the Bates-stamped documents it was unable to locate, (ii) provided additional background on a Swedish document related to Mundipharma, and (iii) reiterated that the Debtors were unable to locate the requested Naloxone studies. Attached hereto as **Exhibit 6** is a true and correct copy of the email from J. Knudson to K. Thompson, dated September 30, 2020.

8. On November 12, 2020, the Debtors received the NASC's second draft Rule 2004 Motion seeking discovery with respect to eighteen categories (including subcategories) of documents and searches, including internal, external, and public medical and scientific information, data, and studies. In advance of a meet and confer on November 20, 2020, the Debtors provided the NASC with a list of scientific information already produced, as well as corresponding Bates ranges. This information, which the NASC has had access to since no later than April 24, 2020 (though I understand that it was likely first given access to most, if not all, of these documents in the MDL by a claimant or plaintiff group before this date), includes (i) the complete set of NDA files for OxyContin, Hysingla ER, and Butrans, (ii) the INDA for OxyContin, (iii) various rat, rabbit, and aberration studies related to oxycodone, (iv) documents from Purdue's publications database, which reflect Purdue's internal review of scientific research by Purdue or Purdue employees being evaluated for publication, (v) reprints of scientific publications that were approved for distribution to prescribers by sales representatives for

November 2008 through January 2017, (vi) Adverse Event Reports, and (vii) MedWatch Reports. Attached hereto as **Exhibit 7** is a true and correct copy of the email from J. McClammy to H. Israel, dated November 20, 2020.

9. On November 21, 2020, the NASC requested (i) clarification on certain Bates ranges and an “index” of the produced INDA for OxyContin due to the size of the document, (ii) confirmation of the Debtors’ proposal for the NASC to coordinate with Creditors’ Committee, and (iii) contact information for Mundipharma’s counsel. Attached hereto as **Exhibit 8** is a true and correct copy of the email from D. Creadore to J. McClammy, dated November 21, 2020. On November 23, 2020, the Debtors provided the NASC with all of the above-requested information, with the exception of the index. Attached hereto as **Exhibit 9** is a true and correct copy of the email from J. Knudson to D. Creadore, *et al.*, dated November 23, 2020. At this time, the Debtors believed that the NASC was coordinating with the Creditors’ Committee as agreed.

10. On December 4, 2020, co-counsel received and forwarded to me a courtesy copy of another version of the NASC’s Rule 2004 Motion.

11. On December 21, 2020, the Debtors met and conferred with the NASC, during which the NASC again committed to follow the process for seeking additional discovery that it had agreed to during the November 20, 2020 meet and confer. Pursuant to the agreement, the NASC agreed to coordinate with the Creditors’ Committee to run search terms on the Creditors’ Committee and Sackler Families databases. Attached hereto as **Exhibit 10** is a true and correct copy of the email from J. Knudson to the Hon. Robert D. Drain, dated December 22, 2020. The Debtors agreed to confirm with the Creditors’ Committee that any documents that hit on the NASC’s search terms could be made available to the NASC counsel.

12. On January 19, 2021, the NASC's search terms returned approximately 264,000 Debtor documents, which the NASC was to receive that week. Attached hereto as **Exhibit 11** is a true and correct copy of the email from D. Creadore to the Hon. Robert D. Drain, dated January 19, 2021. The Debtors understand that the NASC received the Debtors' documents from the Creditors' Committee in late January but, as of this date, we have not been informed that a review of those documents has been completed.

13. On January 7, 2021, before receiving the documents from the Creditors' Committee productions, the NASC requested a meet and confer to discuss the results of the search term hits and a new request for information concerning "discount card data." Attached hereto as **Exhibit 12** is a true and correct copy of the email from D. Creadore to J. Knudson & J. McClammy, dated January 7, 2021. The Debtors suggested that a meet and confer would be more productive after the NASC received and completed its review of the documents, the Debtors met and conferred with the NASC on January 8, 2021. Attached hereto as **Exhibit 13** is a true and correct copy of the email from J. Knudson to D. Creadore dated January 7, 2021.

14. On January 14, 2020, the NASC provided additional information regarding what it called "Purdue's Prescription Discounts Program," and requested that the Debtors provide any information in Purdue's possession related to whether the birth mothers of the NASC's clients had a prescription for a Purdue opioid in the past. Attached hereto as **Exhibit 14** is a true and correct copy of the email from D. Creadore to J. Knudson & J. McClammy, dated January 14, 2021.

15. During meet and confers on January 19, 2021, and January 27, 2021, the Debtors explained to the NASC that Purdue, as a pharmaceutical manufacturer, does not maintain underlying patient information in any standalone database or other consolidated form (to the

extent that it is in possession of it). Rather, the Company has general information about E-voucher and rebate card programs and the healthcare providers who use those programs. The NASC was not satisfied with this response. In an effort to continue assisting the NASC as much as they reasonably could, the Debtors offered to run birth mother names through various Company databases if the NASC would provide that information. Although, the NASC accepted this offer, it did not provide the Debtors with the requested list of names.

16. On January 29, 2021, at the NASC's request for a written response explaining exactly what type of information Purdue has with respect to patient-level data, the Debtors followed up with an email response reiterating that Purdue does not maintain a comprehensive database of patient-identifying information. Attached hereto as **Exhibit 15** is a true and correct copy of the email from J. McClammy to D. Creadore & J. Knudson, dated January 29, 2021. After inquiring with the Company and conducting a number of searches, the Debtors determined that the discount card program data in Purdue's possession does not have the patient-identifying data (including patient name) necessary to determine whether the birth mothers of the NASC's clients had a Purdue prescription. Purdue's data includes the patient's age and gender and information about the prescription itself, but it does not include patient names. Again, subject to HIPAA and other privacy limitations, the Debtors offered to run searches for names of possible patients for which the NASC was seeking this information if it would provide those names. The NASC, again, accepted this offer but did not provide the Debtors with the list of names, instead referring them to Prime Clerk to determine the right names. Attached hereto as **Exhibit 15-1** is a true and correct copy of the email from S. Bickford to J. McClammy, dated February 2, 2021.

17. In early February, with the assistance of Prime Clerk and the Company, the Debtors compiled a list of the NASC's clients from their submitted proofs of claim, chose a

random sample of thirty (30) claimants who provided the birth mother's name, and ran those names through Purdue's adverse event database. The search yielded zero results. Despite the sample search returning zero hits, the Debtors offered to run the search for all of the NASC's clients who provided a birth mother name, if the NASC would first obtain and provide HIPAA releases from those individuals to ensure that any information found could be disclosed.

Attached hereto as **Exhibit 16** is a true and correct copy of the email from J. Knudson to D. Creadore, dated February 12, 2021. To date, the NASC has not provided the requested HIPAA releases.

18. On February 10, 2021, while discussions concerning the "discount card data" were still ongoing, the NASC approached the Debtors with another discovery request for information regarding a "Central Repository Stamford, CT." Attached hereto as **Exhibit 17** is a true and correct copy of the email from D. Creadore to J. McClammy & J. Knudson, dated February 10, 2021. Cites to volumes of the "Central Repository Stamford, CT" in produced documents apparently led the NASC to hypothesize that this referred to a standalone repository containing various scientific studies and/or scientific databases. The Debtors reached out to several current Purdue employees in the Company's regulatory group concerning the "Central Repository Stamford," who confirmed that (i) the "Central Repository Stamford" does not exist now, and (ii) there is no repository of regulatory documents or scientific studies *other than* those submitted to the FDA. The Debtors also searched for references to the "Central Repository Stamford" in Purdue's email archive, which contains every email to and from the Company for the last fifteen or twenty years. The Debtors found no meaningful reference to the "Central Repository Stamford." Aside from citations, the only discussions regarding the "Central Repository Stamford" were Purdue employees asking what it was and/or noting that they had

never heard of it. (*See, e.g.*, Rule 2004 Reply, Ex. G.) However, the Debtors did find that the referenced volume 105 of the “Central Repository Stamford, CT” was a 353-page document produced a number of times that was marked as being part of a “New Drug Application.” The Bates numbers where that document could be found were provided to the NASC. Attached hereto as **Exhibit 18** is a true and correct copy of the email from J. McClammy to D. Creadore & J. Knudson, dated February 16, 2021.

19. The Debtors conveyed the results of their searches during a met and confer on February 16, 2021, and followed up with an email on February 17, 2021, reiterating that (i) the Debtors’ searches did not identify any evidence that a “Central Repository Stamford, CT” exists today or existed within the past twenty years, (ii) certain volumes labeled (for whatever reason) as “Central Repository Stamford, CT” have been produced and many appear to refer to the same 353-page document that is also marked as being part of a “New Drug Application” submitted to the FDA, (iii) the Debtors are not aware of relevant studies that have not already been produced in the millions of documents made available to the NASC, and (iv) if the NASC would provide a reasonable level of detail regarding the studies it seeks, the Debtors would conduct additional reasonable searches. Attached hereto as **Exhibit 19** is a true and correct copy of the email from J. Knudson to D. Creadore, *et al.*, dated February 17, 2021.

20. The NASC next requested a “sworn statement” regarding the “Central Repository Stamford, CT” and another meet and confer. Attached hereto as **Exhibit 20** is a true and correct copy of the email from D. Creadore to J. Knudson, dated February 22, 2021. The Debtors participated in another meet and confer with the NASC on February 25, 2021, during which the Debtors explained their unsuccessful searches for a “Central Repository Stamford, CT” through an index of paper archives. The Debtors reached out to additional current and former employees

on the topic of the “Central Repository Stamford, CT” but none had heard of it. The Debtors learned that the “Central Repository Stamford, CT” could potentially refer to paper copies of files submitted to the FDA, including any studies, in line with industry practice. However, such FDA submissions have been scanned into electronic files and the relevant electronic files would be among the materials made available to the NASC.

21. On March 10, 2021, the Debtors received a draft of the NASC’s Rule 2004 Reply with three requests for production identical to the Proposed Requests filed with the Rule 2004 Reply. On March 12, 2021, the Debtors attempted to resolve the two outstanding requests in the NASC’s Rule 2004 Reply (other than the “Central Repository Stamford, CT” issue, which the Debtors believed was a “closed” issue based on the searches described in paragraphs 18 and 20). Attached hereto as **Exhibit 21** is a true and correct copy of the email from J. Knudson to D. Creadore, dated March 12, 2021. With respect to the request for CCDS, the Debtors informed the NASC that a large number of CCDS have already been produced and suggested that it examine those documents. The Debtors also offered to (i) produce other relevant CCDS to the extent they have not already been produced and (ii) direct the NASC to CCDS in the productions if it is unable to find them. With respect to the scientific studies, the Debtors (i) pointed the NASC to the “non-GLP” study referenced in the Rule 2004 Reply (Rule 2004 Reply ¶ 8), and (ii) again offered to search for additional studies that the NASC specifies with a reasonable level of detail.

22. Upon further review of the productions to which the NASC has access, the Debtors have produced all of the CCDS for Oxycodone Hydrochloride from 2000 through 2017, all of the CCDS for Buprenorphine Base Transdermal System from 2001 through 2016, and

multiple copies of at least one (1) version of the Hydromorphone CCDS.³ Attached hereto as **Exhibit 22** is a true and correct copy of the March 31, 2021 Email from J. Knudson to J. McClammy and D. Creadore.

23. On March 16, 2021, the NASC requested that the Debtors make available for deposition non-Debtor employees from “Springhorn [sic] Laboratory, International Research and Development Corporation, [and] Pharmakon Research International,” as well as “Purdue’s Director of Drug Safety Evaluation, and a member of the Drug Risk Management Group.” Attached hereto as **Exhibit 23** is a true and correct copy of the email from D. Creadore to J. Knudson and J. McClammy, dated March 16, 2021.

24. The Debtors engaged in two additional meet and confers on March 15, 2021, and March 19, 2021, but neither were successful in resolving the remaining issues. Attached hereto as **Exhibit 24** is a true and correct copy of the email from D. Creadore to J. Knudson, dated March 19, 2021.

25. Attached hereto as **Exhibit 25** is a true and correct copy of a periodic safety update report for oxycodone hydrochloride dated December 10, 2009, Bates-stamped PURCHI-000028743.

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³ Although not named in the request, the Debtors also had already produced all of the CCDS for Hydrocodone Bitartrate (Hysingla) from 2015 through 2017.

Dated: April 1, 2021
New York, New York

/s/ James I. McClammy

DAVIS POLK & WARDWELL LLP

450 Lexington Avenue

New York, New York 10017

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